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Atty. Dkt. No. 074129-0516

XV

**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Kazumichi YAMAMOTO et al.  
Title: PROCESS FOR PRODUCING SUSTAINED-  
RELEASE COMPOSITION  
Appl. No.: 10/518,914  
Filing Date: 12/23/2004  
Examiner: Unassigned  
Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

Some of the documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. Copies of these documents (Documents A20, A21, A23 – A26, A31 – A35 and A38 – A46) are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and JPO. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

An English-language abstract of the foreign-language documents A30 and A47 have been provided. Consequently, the foreign language documents have been submitted in compliance with the PTO requirements and, therefore, the documents should be considered by the Examiner (37 CFR §1.97, §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 12, 2005

By \_\_\_\_\_

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Attorney for Applicants  
Registration No. 44,250

Substitute for form 1449B/PTO

**Date Submitted:** April 12, 2005

*(use as many sheets as necessary)*

Sheet	1	of	2
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<b>Application Number</b>	10/518,914
<b>Filing Date</b>	12/23/2004
<b>First Named Inventor</b>	Kazumichi YAMAMOTO
<b>Group Art Unit</b>	Unassigned
<b>Examiner Name</b>	Unassigned
<b>Attorney Docket Number</b>	074129-0516

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	2002/0198315	A1	Hutchinson	12/26/2002	
	A2	2003/0134800	A1	Yamamoto et al.	07/17/2003	
	A3	2004/0121008	A1	Shiraishi et al.	06/24/2004	
	A4	4,211,769		Okada et al.	07/08/1980	
	A5	5,134,122		Orsolini	07/28/1992	
	A6	5,575,987		Kamei et al.	11/19/1996	
	A7	5,716,640		Kamei et al.	02/10/1998	
	A8	5,773,032		Engel et al.	06/30/1998	
	A9	5,581,451		Takechi et al.	12/22/1998	
	A10	5,889,110		Hutchinson	03/30/1999	
	A11	6,034,175		Hutchinson	03/07/2000	
	A12	6,036,976		Takechi et al.	03/14/2000	
	A13	6,045,830		Igari et al.	04/04/2000	
	A14	6,113,943		Okada et al.	09/05/2000	
	A15	6,346,274	B1	Koll et al.	02/12/2002	
	A16	6,599,519	B1	Seo et al.	07/29/2003	
	A17	6,740,634	B1	Saikawa et al.	05/25/2004	

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A18	EP	0 145 240	A2	Takeda Chem. Ind., Ltd.	06/19/1985		
	A19	EP	0 190 833	A2	Tadede Chem. Ind., Ltd.	08/13/1986		
	A20	EP	0 505 966	A1	Hoechst AG.	09/30/1992		Abs
	A21	EP	0 586 238	A2	Takeda Chem. Ind., Ltd.	03/09/1994	Corresponds to USP 5,575,987 and USP 5,716,640	
	A22	EP	0 626 170	A2	Sandoz Ltd.	11/30/1994		
	A23	EP	0 761 213	A2	Takeda Chem. Ind., Ltd.	03/12/1997	Corresponds to USP 6,045,830	
	A24	EP	0 779 072	A1	Takeda Chem. Ind., Ltd.	06/18/1997	Corresponds to USP 5,851,451 and USP 6,036,976	
	A25	EP	0 781 548	A2	Takeda Chem. Ind., Ltd.	07/02/1997		
	A26	EP	0 839 525	A1	Takeda Chem. Ind., Ltd.	05/06/1998	Corresponds to USP 6,113,943	
	A27	EP	1 197 208	A1	Takeda Chem. Ind., Ltd.	04/17/2002		
	A28	EP	1 413 315	A1	Takeda Chem. Ind., Ltd.	04/28/2004		
	A29	EP	1 424 080	A1	Takeda Chem. Ind., Ltd.	06/02/2004		

Date  
Considered

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: April 12, 2005 (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/518,914
				Filing Date	12/23/2004
				First Named Inventor	Kazumichi YAMAMOTO
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	074129-0516
Sheet	2	of	2		

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A30	JP	06-065053		Shiseido Co., Ltd.	03/08/1994		Abs
	A31	JP	11-116499		Asahi Chemical Industry Co., Ltd.	04/27/1999		Abs
	A32	JP	2000-143533		Asahi Chemical Industry Co., Ltd.	05/23/2000		Abs
	A33	JP	2003-171264		Taiyo Yakuhi Kogyo KK.	06/17/2003		Abs
	A34	JP	2003-252751		Takeda Chem. Ind., Ltd.	09/10/2003		Abs
	A35	PCT	WO 93/024150		Zenca Ltd.	12/09/1993	Corresponds to US 2002/0198315, USP 5,889,110 and USP 6,034,175	
	A36	PCT	WO 98/32423		Takeda Chem. Ind., Ltd.	07/30/1998		
	A37	PCT	WO 99/12549		Danbiosys UK. Ltd.	03/18/1999		
	A38	PCT	WO 00/033809		Mediolanum Farm Spa	06/15/2000		
	A39	PCT	WO 00/040259		Dong Kook Pharm. Co., Ltd.	07/13/2000		
	A40	PCT	WO 01/005379		Samyang Corp.	01/25/2001	Corresponds to USP 6,599,519	
	A41	PCT	WO 02/074340	A1	Takeda Chem. Ind., Ltd.	09/26/2002		Abs
	A42	PCT	WO 03/002091	A2	Takeda Chem. Ind., Ltd.	01/09/2003		
	A43	PCT	WO 03/002092	A2	Takeda Chem. Ind., Ltd.	01/09/2003	Corresponds to US 2003/134800	
	A44	PCT	WO 01/083594	A1	Tanabe Seiyaku Co., Ltd.	01/22/2003	Corresponds to EP 1 277 787	
	A45	PCT	WO 03/013609	A1	Takeda Chem. Ind., Ltd.	02/20/2003		Abs
	A46	PCT	WO 03/015820	A1	Takeda Chem. Ind., Ltd.	02/27/2003		Abs

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A47	OKADA, Hiroaki, "Dosage and Design of leuproreline Acetate Microspheres for Long-term Sustained-release Injection", <i>Pharm Tech Japan</i> , Vol. 14, No. 1, 1998, pgs. 75-88.		
	A48	WOO, Byung H., " <i>In Vitro</i> Characterization and <i>in Vivo</i> Testosterone Suppression of 6-Month Release Poly(D,L-Lactide) Leuprolide Microspheres", <i>Pharmaceutical Research</i> , Vol. 19, No. 4, April 2002, pgs. 546-550.		

Examiner Signature	Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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